U.S. Measurement System

NIST National Institute of Standards and Technology

Imaging as a Biomarker: Standards for Change Measurements in Therapy

Breakout Area 5: Resources for Qualification of Imaging Systems: Benchmarking of Imaging Processing and Data Integration Tools and Related Statistical Methods

Day 1: Summary of "Big Picture Roadmapping – The What by When?" Near, Mid and Long-Term Issues

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All Timeframes near, mid, long

1. ***Large public datasets with data, imaging parameters and protocols in standard format***
   - ❑ Impact of Success:
     - New and improved tools
     - Standardize/optimize annotation and truthing
     - New clinical understanding and insight
     - Better understanding of biological variability
     - Appropriate training/test data
       - How/when to sequester data
     - Many customers beyond MI/PhRMA companies
   - ❑ Technical Barriers:
     - Need to establish/unify measures of response
     - Effort by clinicians to provide nonstandard information
       - Defining truth and acquiring annotations
     - Need for different data for different diseases
     - Continuous effort to acquire data
     - Where/how to host data?
     - Support from patient, health insurance companies
   - ❑ Key Players: NIH, NEMA, RSNA, ACR, Clinical centers, PhRMA, NIST

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Near-Term 1-3 Years

1. Phantoms for characterization of systems and tools

- Impact of Success:
  - Improved harmonization of image protocols
  - Improved methodology for harmonizing output from various imaging systems or tools
  - Better understanding of avoidable bias and variability
  - Improve quantization of data
  - Metrics for measuring accuracy and precision of algorithms
- Technical Barriers:
  - Different phantoms for different application
  - Different phantoms for qualification of single system, cross-validation of multiple systems, QA applications, etc
  - Want to avoid a overly strict requirements
  - Lack of meaningful measures of performance
  - Added cost must balance value
- Key Players: NIST, Academics community, AAPM, NEMA, PhRMA

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Near-Term 1-3 Years

1. Human phantoms (rescan of the patient)

- Impact of Success:
  - Help in precision of the study
  - Identify sources of technical variability (controls for biological variability)
- Technical Barriers:
  - Ethics, may not be appropriate for all imaging or patients
  - Could increase time and expense for studies
- Key Players: NIST, MI vendors, FDA, Pharma

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Near-Term 1-3 Years

1. ***Methods/tools for monitoring systems (imaging equipment) to detect, correct drift and detect of study flaws***
   - ❑ Impact of Success:
     - Improved trial monitoring and control
     - Improve data quality by reducing unusable/unreadable data
   - ❑ Technical Barriers:
     - Set of automated tools would be ideal for this
     - May need additional scanner information
   - ❑ Key Players: Software companies, MI companies, Pharma, CRO, FDA

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Very Near-Term 1-3 Years

1. ***Workshops to unify patient prep and imaging protocols***
   - ❑ Impact of Success:
     - Reduced variability in clinical trials
     - Potential to improved diagnostic/screening imaging
   - ❑ Technical Barriers:
     - Human factor
       - Hard to get techs/MDs to change
     - This has been started and should be continued
   - ❑ Key Players: Clinical Societies, NEMA, PhRMA